CANADA

Highlight of Developments since the 3rd Meeting of the WPMN

The following activities have taken place since the 3rd meeting of the OECD Working Party on Manufactured Nanomaterials in November 2007:

- Environment Canada and Health Canada issued the government response to the first multi-stakeholder workshop (September 2007). Major outcomes from the workshop include a decision to issue a mandatory information gathering survey under the authority of the Canadian Environmental Protection Act, 1999, and significant discussion on potential considerations and approaches for implementing an effective regulatory framework for nanomaterials.

- Environment Canada and Health Canada are targeting September 2008 for the launch of the information gathering survey under the authority of Section 71 of CEPA 1999. The objective of this survey is to gather use pattern information, including volumes and sectors of use, and any relevant toxicological data already available for nanomaterials already in or soon to enter commerce in Canada. In parallel to the mandatory survey, a voluntary initiative will be pursued to gather additional information such as stewardship practices and physical chemical property data. See Section 2.

- Environment Canada held discussions with departmental researchers (January 2008) to initiate the development of a research strategy on environmental and ecological issues of nanomaterials in support of legislative and regulatory mandates of the department. See Section 5.

- The Canadian Institute of Health Research, in conjunction with various federal government departments, held a workshop to examine the nano ethical, economic, environmental, legal, and social issues (January, 2008). See Section 5.

- In the area of scientific research, funding for two environmental effects projects have been approved and the research consortiums held two meetings (March and April 2008) to discuss the scope and research issues, as well as areas of collaboration and cooperation. See Section 5.

- In the area of policy research, the Council of Canadian Academies will issue in June 2008 an assessment of the current state of knowledge of potential human health and environmental risks of nanotechnology.

1. Regulatory Developments in Canada

Federal government actions

The first multi-stakeholder workshop was hosted by Environment Canada and Health Canada (September 2007) brought together representatives from government, industry, public interest groups, and academia to obtain feedback on a proposed regulatory approach for nanomaterials under the Canadian Environmental Protection Act, 1999. The government will soon issue a response to the workshop which includes a decision to issue a mandatory information gathering survey under the authority of the Canadian Environmental Protection Act, 1999; significant discussion on approaches for implementing an effective regulatory framework for nanomaterials; and considerations for improved engagement of and communication with stakeholders.
The proposed regulatory framework for nanomaterials under the Canadian Environmental Protection Act, 1999 has been expanded to include both regulatory and research considerations. At this time, planned regulatory activities include:

**Phase 1 (started fall 2006):**
1. Continue work with international partners to develop scientific and research capacities (OECD, ISO).
2. Inform potential notifiers of their regulatory responsibilities under the current framework.
3. Develop initiatives to gather information from industry on the uses, properties, and effects of nanomaterials.
4. Consider whether amendments to CEPA 1999 or the NSNR would be needed to facilitate the risk assessment and management of nanomaterials.

**Phase 2 (2008 – 2010):**
1. Resolution of standard nomenclature and terminology by the ISO.
2. Consider establishing specific data requirements for nanomaterials under the NSNR.
3. Consider the use of Significant New Activity notices for substances already on the DSL.

Canada, through Environment Canada, is the lead for the ISO TC229 WG1 Task Group on Nomenclature. This Task Group includes representatives from the United States, Japan, Germany, the Chemical Abstracts Service, and IUPAC, and includes regulators, industry, and academia. The Group is tasked with developing a nomenclature system which meets the needs of regulators, industry, and academia. Representatives from the nomenclature taskforce presented a discussion on the definition of nomenclature as well as nomenclature needs from regulatory, industrial and academic perspectives at the ISO TC 229 meeting in May 2008 (Bordeaux, France).

Canada, through NRC-CISTI (National Research Council – Canada Institute for Scientific and Technical Information) is developing, under ISO TC/229 JWG1, a taxonomy system for nanomaterials which involves an intelligent organization of terms used in various communities pertaining to nanomaterials (e.g., tubes, rods, nanoscale, etc). Also, Canada through NRC-SIMS (National Research Council – Steacie Institute for Molecular Sciences) is proposing to lead a project to develop definitions for core terms resulting from the taxonomy system.

**2. Developments on Voluntary or Stewardship Schemes in Canada**

Based on the discussions at the multi-stakeholder workshop (September 2007), Environment Canada and Health Canada opted to conduct a mandatory survey under the authority of Section 71 of the Canadian Environmental Protection Act, 1999. The information gathering effort will focus on obtaining information on nanomaterials from industry and on building a knowledge base to inform risk assessment and management approaches.

Respondents will be required to submit information on:

- Identification of nanomaterials in or soon to enter Canadian commerce;
- Basic use patterns including volumes, sectors of use, types of products; and
- Any toxicological data available.
In parallel, a voluntary initiative is planned to gather more specific information such as stewardship practices and physical-chemical property data. Environment Canada and Health Canada are working toward harmonization and facilitated information exchange with the US EPA.

The Canadian approach will be informed by discussions within Steering Group 5 of the WPMN.

**Nanotechnology Market Penetration in Canada**

There is a limited understanding of the current Canadian market for nanotechnology. A formal use pattern survey and product inventory has not been conducted for Canada; however, Industry Canada has undertaken some preliminary investigations.

Industry Canada has examined its Strategis database and conducted independent web searching to identify Canadian companies engaged in nanotechnology. Industry Canada also contracted a study, in collaboration with Environment Canada, Health Canada, and the Canadian Food Inspection Agency, to investigate US companies exporting nanotechnology-related products to Canada.

Analysis of all the data collected through these projects identified 79 domestic companies with 107 distinct product lines and 63 US companies which include Canada in their business with 127 distinct products lines. Of the 234 product lines, 151 had nanomaterial identity information available on-line and these products represented 88 distinct nanomaterials with 85 distinct uses. The products included a range of constituent nanomaterials, including elemental, alloy, carbon-based, and mineral nanomaterials. Furthermore, these nanomaterials represent a range of industrial sectors including consumer products, life sciences, chemicals, plastics, semiconductors, construction, transportation, security, energy, earth science and environment.

**3. Risk Assessment Decisions**

A small number of notifications have been received by some regulatory programmes.

- **Industrial or commercial chemicals**
  - In December 2007, the Minister of the Environment Canada issued a Significant New Activity Notice for a substance identified as a nanomaterial. The Notice requires the submission of additional, prescribed data if the substance will be used for a purpose other than the notified use which will allow Environment Canada and Health Canada to assess potential risks.

- **Pharmaceuticals**
  - Two nanomedicines have received approval from Health Canada under the current regulations and policies.

- **Pesticide applications**
  - Some inquiries have been made, but no notifications have been submitted.

- **Food related applications**
  - Some food related applications in the natural health products field are currently under review by Health Canada.
  - No notifications on food additives or food packaging have been received to date.

- **Others**
  - No notifications with respect to fertilizers, veterinary biologics, or animal feed have been received to date.
4. Developments of Good Practice Documents

The Workplace Hazardous Materials Information System (WHMIS) is implemented through coordinated federal, provincial and territorial (FPT) legislation. Supplier labeling and Material Safety Data Sheet (MSDS) requirements are set out under the Hazardous Products Act (HPA) and associated Controlled Products Regulations. The HPA and its regulations are administered by Health Canada. The compliance and enforcement program for the WHMIS supplier labeling and MSDS requirements of the HPA is conducted by the 13 FPT Occupational Safety and Health (OH&S) agencies in Canada in conjunction with the WHMIS employer requirements established by these 13 OH&S agencies. To ensure Canadian workers are protected from possible hazards specific to manufactured nanomaterials, a WHMIS working group has been set up. A number of FPT OH&S representatives sit on the working group. The objective of this Nanomaterials WHMIS Working Group is to investigate the possible need to:

1. Implement changes to WHMIS hazard criteria to address manufactured nanomaterials,
2. Implement changes to WHMIS disclosure requirements on MSDSs; and/or
3. To develop guidelines or best practices for workers in the field of nanotechnology with a view to publishing these document on Health Canada’s national WHMIS website.

Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST) has developed two documents for occupational safety: (1) Development of a best practices guide for the safe handling of nanoparticles; and (2) safe handling of nanomaterials. These documents are a combination of similar documents developed around the world. ISO TC/229 WG3 will be putting forth similar documents with support from IRSST to get an ISO standard for safe handling of nanomaterials for workers.

5. Research in Canada

Scientific research

Environment Canada supported two projects under the Strategic Grants Program of the Natural Sciences and Engineering Research Council (NSERC) which were approved in September 2007. The first project will focus on aqueous related research examining the fate and effects of nanomaterials on aquatic invertebrates, characterize their physiological effects, in addition to developing detection and characterization methodology. The second project will focus on the terrestrial fate of nanomaterials including toxicity to sentinel organisms (such as earthworms), particle transformation, and transport. Another objective of this research is to develop predictive tools generalized for nanoparticles.

In May 2008, a three-year joint Health Canada-Environment Canada project will focus on developing analytical tools and test methods for biomonitoring of nanomaterials in products covered under the Food and Drugs Act (e.g., pharmaceuticals, personal care products). Both invertebrate and mammalian cell lines will be studied by exposure to well characterized (e.g., physical chemistry) and representative nanomaterials on the OECD list of representative nanomaterials.

Environment Canada laboratories are also conducting some limited research on fate and ecotoxicity of nanomaterials in aquatic systems. A departmental research strategy is under development to focus on ecological and environmental research needs as mandated under the Canadian Environmental Protection Act, 1999. The objectives of the strategy are to build and improve upon research expertise and capacity for nanomaterials.

Health Canada is engaged in both in-house and collaborative research projects involving a range of different nanomaterials (zero-valent iron nanoparticles, nanoparticulate carbon black and nanoparticulate
quartz, single walled carbon nanotubes, and C₆₀ fullerenes). Testing includes pulmonary and cardiovascular injury; reproductive and development effects; exposure and tissue penetration, interactive effects with microorganisms, and genotoxicity. In vitro techniques play an important part of the repertoire for such investigations. In line with expected goals for a forthcoming broader inter-departmental initiative, Health Canada is working with Environment Canada to help establish a research capacity to support regulation of manufactured nanomaterials (i.e., in regulation, health and safety monitoring, and ecotoxicology). This would also be in support of international EHS and R&D efforts, and involve the application of new tools for those priority nanomaterials identified by OECD countries and consistent with directions that OECD and ISO work is taking.

The National Research Council of Canada is involved in research and development of nanotechnologies on a wide range of topics which probe our fundamental understanding of their physical and chemical properties to areas of fabrication and application. Research is ongoing to develop capabilities for measurement and characterization of nanomaterials and nanoscale features. Canada is actively involved in international R&D collaborations with the USA and other countries. The National Research Council of Canada-Taiwan partnership focuses on research projects which underpin and apply nanotechnologies, one of which involves the development of techniques and instrumentation for accurate primary calibration of nanoscale length for application in scanning probe microscopy. Cooperation and harmonization of accurate measurement techniques and calibrations aid in establishing internationally-recognized client services and measurement capabilities.

The National Research Council of Canada (NRC) has launched new R&D initiatives which support collaborative projects between Institutes (http://www.nrc-cnrc.gc.ca/institutes/index_e.html). These cross-Institute Programs in Nanotechnology exploit the multi-disciplinary strengths of the NRC with focus on fundamental R&D topics which underpin EHS research. One of the supported projects focuses on: airborne nanoparticles (nano-aerosols) that contribute to poor air quality.

Policy research

The Council of Canadian Academies is a non-profit organization which acts as a source of independent, expert assessment of the science underlying pressing issues and matters of public interest. The Council is undertaking an assessment of the current state of knowledge regarding the health and environmental risks potentially associated with nanotechnology. This work began in February 2007 and the report will be delivered to Health Canada on June 2, 2008, with a public release shortly thereafter.

Canadian Institutes for Health Research, in partnership with Natural Sciences and Engineering Research Council, the Social Sciences and Humanities Research Council of Canada, Health Canada, Environment Canada, Industry Canada, and other federal departments, held a workshop on nanotechnology in January 2008. The workshop promoted discussion on developments in the field of nanotechnology and the policy challenges that they may present (i.e., nano ethical, economic, environmental, legal, and social issues (NE’LS)). The workshop identified a number of research priorities in the field of nanotechnology and health impacts, for consideration by various participating agencies and departments.

6. Public and Stakeholder Consultations

Environment Canada and Health Canada hosted a multi-stakeholder workshop on a proposed regulatory framework for nanomaterials under the Canadian Environmental Protection Act, 1999 involving industry, non-governmental organizations, academia, and other interested parties in September 2007. Additional consultative meetings will be conducted as part of the normal process in the development of a regulatory regime for nanomaterials.